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August 21, 2019

#### Via ECF

Jonathan J. Lerner, Esq. Discovery Master Pilgrim Mediation Group 4 Times Square New York, New York 10036

Re: In Re Effexor XR Antitrust Litigation

Civil Action No.: 3:11-cv-5479-PGS-LHG (Lead)

Dear Discovery Master Lerner:

I write on behalf of Plaintiffs in response to your August 15, 2019 letter (ECF No. 613).

All of the issues raised in Plaintiffs' Motion to Compel (ECF No. 581) remain unresolved. Despite additional meet and confers since the filing of the Motion to Compel (as contemplated in ECF No. 587), Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Limited (together, "Zydus") have not produced any additional documents since March 27, 2019, when the Motion to Compel was filed. Thus, Plaintiffs respectfully request that you rule on the Motion to Compel, to which Zydus has filed no opposition or response.

Respectfully submitted,

/s/ Peter S. Pearlman

Peter S. Pearlman

PSP:mds Enclosure

cc: All Counsel of Record (W/Encl. via ECF)

# EXHIBIT A

#### **Luke Smith**

From: Luke Smith

**Sent:** Monday, June 24, 2019 8:36 AM

To: Nealon, James

**Cc:** Caitlin G. Coslett; Neill Clark

**Subject:** RE: Effexor- call with Zydus counsel re subpoena

Jim, just wanted to create a record here that I've called you five times and left multiple voicemails and messages with your assistant since I sent my four unanswered emails below, but have heard nothing back.

From: Luke Smith

Sent: Wednesday, June 5, 2019 3:01 PM

To: Nealon, James < James. Nealon@withersworldwide.com>

Cc: Caitlin G. Coslett <ccoslett@bm.net>; Neill Clark <nclark@faruqilaw.com>

Subject: RE: Effexor- call with Zydus counsel re subpoena

Jim, I just left you a voicemail on this.

Please get back to me ASAP.

If I don't hear from you by tomorrow I will assume we need to ask the Court for a ruling on our motion. (Note that I just corrected the subject to Effexor from Zetia; my apologies for any confusion caused by that.)

A. Luke Smith Radice Law Firm

Office: (267) 570-3000 Mobile: (267) 738-0407 <u>www.radicelawfirm.com</u>

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From: Luke Smith

Sent: Tuesday, May 28, 2019 3:10 PM

To: 'Nealon, James' <James.Nealon@withersworldwide.com>

Cc: 'Caitlin G. Coslett' <ccoslett@bm.net>; 'Neill Clark' <nclark@farugilaw.com>

Subject: RE: Zetia - call with Zydus counsel re subpoena

Jim, I'm following up once more on below.

By end of day tomorrow, please commit to a date certain by which Zydus will produce transactional sales data and the other categories of information set forth below.

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From: Luke Smith

Sent: Monday, May 20, 2019 7:29 PM

To: Nealon, James < James. Nealon@withersworldwide.com >

Cc: Caitlin G. Coslett <ccoslett@bm.net>; Neill Clark <nclark@farugilaw.com>

Subject: RE: Zetia - call with Zydus counsel re subpoena

Jim, please advise the status of Zydus's promised production ASAP.

From: Luke Smith

Sent: Thursday, May 9, 2019 10:41 AM

To: Nealon, James <James.Nealon@withersworldwide.com>

Cc: Caitlin G. Coslett < ccoslett@bm.net >; Neill Clark < nclark@faruqilaw.com >

Subject: Re: Zetia - call with Zydus counsel re subpoena

Jim,

Thanks for the call last week. I had expected to hear from you by now authorizing us to produce the Niaspan data to you, and producing the ANDA file. Please advise status as soon as possible.

Here's a summary of what we discussed and what we understand you agreed to on behalf of Zydus:

Sales data: seek authorization from Zydus for us to share with you the data Zydus previously produced to us regarding its Niaspan sales, to guide your efforts to expeditiously produce similar sales data for Effexor XR.

ANDA file: produce Zydus's ANDA file (incl. emails and telephone contact reports with FDA) within a week, which we'll review for adequacy and completeness; we reserve rights to follow up with requests forregulatory planning/prioritization documents that may be outside the ANDA file.

Forecasts and launch projections: search for pre-settlement forecasts and launch date projections, i.e., those from the time Zydus filed its ANDA in 2007, through its launch in April 2011 (note Zydus has already produced several forecasts, but even the earliest such forecast references Zydus settlement with Wyeth; we're particularly interested in forecasts and launch projections generated prior to that agreement).

Manufacturing: search for (a) documents showing Zydus's planning and execution of scaleup, process validation, and launch build for its 2011 launch, and (b) documents sufficient to show Zydus theoretical capacity to manufacture launch quantities as early as June 2008 through its 2011 launch, including documents showing the availability of capacity at the relevant facility, equipment, line, raw materials, FDA cGMP compliance, as well as potential to add shifts if needed, and any procedures for prioritizing one product over another if needed to capitalize on high value launch opportunities.

Settlement/negotiation: search for documents concerning Zydus's settlement of its Effexor XR litigation, including all documents exchanged between Zydus on the one hand, and Wyeth, Teva, and/or any othergeneric Effexor XR ANDA filer on the other hand. As a starting point, we suggest searching the custodial files of Joseph D. Renner and Pankaj R. Patel for Effexor or venlafaxine. If you know of additional custodians likely to possess responsive documents, please include them.

A. Luke Smith Radice Law Firm

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From: Nealon, James <James.Nealon@withersworldwide.com>

Sent: Thursday, May 2, 2019 3:18:18 PM

**To:** Luke Smith **Cc:** Caitlin G. Coslett

Subject: Re: Zetia - call with Zydus counsel re subpoena

Correct — my mistake

Sent from my iPhone

On May 2, 2019, at 3:09 PM, Luke Smith <smith@radicelawfirm.com> wrote:

We had set this for 3:30. Let's talk then.

From: Nealon, James < <u>James.Nealon@withersworldwide.com</u>>

Sent: Thursday, May 2, 2019 3:01 PM

**To:** Luke Smith < <a href="mailto:lsmith@radicelawfirm.com">lsmith@radicelawfirm.com</a> <a href="mailto:ccs">Cc: Caitlin G. Coslett <a href="mailto:ccs">ccs</a> <a href="mailto:ccs">ccs</a> <a href="mailto:lsmith@radicelawfirm.com">ccs</a> <a href="mailto:css">ccs</a> <a href="mailto:css">css</a> <a hre

Subject: Re: Zetia - call with Zydus counsel re subpoena

Running 3 mins behind

Sent from my iPhone

> On May 1, 2019, at 9:58 AM, Luke Smith < <a href="mailto:lsmith@radicelawfirm.com">lsmith@radicelawfirm.com</a>> wrote:

>

> We can use this dial-in: 866-730-7514,980551#

> <meeting.ics>

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